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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,888	07/14/2003	Donald Jeffery Zack	01107.00369	3409

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EXAMINER

BALLARD, KIMBERLY A

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1649

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/617,888	Applicant(s) ZACK ET AL.	
	Examiner Kimberly A. Ballard	Art Unit 1649	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 July 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-53 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-9, drawn to a method of inhibiting neuronal cell death comprising administering to a subject an effective amount of an isolated molecule comprising an antibody variable region which specifically binds to a neuronal marker protein whereby cell death is inhibited, classified for example in class 424, subclass 130.1.
- II. Claims 10 and 12-19 (in part), drawn to a method of preventing neuronal cell death in a mammal, comprising administering to the mammal a nucleic acid molecule comprising a coding sequence for a neuronal marker protein whereby cell death is inhibited or prevented, classified for example in class 514, subclass 44.
- III. Claims 11 and 12-19 (in part), drawn to a method of preventing neuronal cell death in a mammal, comprising administering to the mammal a purified human neuronal marker protein whereby neuronal cell death is inhibited or prevented, classified for example in class 514, subclass 2.
- IV. Claims 20-28, drawn to a method of identifying regions of neuronal cell death in a patient, comprising administering to a patient an antibody variable region which specifically binds to a neuronal marker and detecting

the detectable moiety in the patient, thereby identifying regions of neuronal cell death, classified for example in class 424, subclass 130.1.

- V. Claims 29 and 34, drawn to a method screening for neuronal cell death in a patient, comprising contacting a body fluid collected from the patient with an antibody variable region which specifically binds to a neuronal marker and detecting the neuronal marker in the sample, classified for example in class 435, subclass 7.1.
- VI. Claims 30-31, drawn to a method of promoting neuronal cell death in a patient, comprising administering to the patient a neuronal marker protein whereby neuronal cell death is stimulated in the patient, classified for example in class 514, subclass 2.
- VII. Claims 32-33, drawn to a method of promoting neuronal cell death in a patient, comprising administering to the patient a nucleic acid molecule encoding a neuronal marker (NM) protein whereby the NM protein is expressed and neuronal cell death is stimulated in the patient, classified for example in class 514, subclass 44.
- VIII. Claim 35, drawn to a method of screening for neuronal cell death in a patient, comprising detecting in a body fluid collected from the patient a nucleic acid encoding a neuronal marker, classified for example in class 435, subclass 6.
- IX. Claims 36 and 37, drawn to a method of identifying candidate drugs for treating neuronal cell death, comprising contacting cells which naturally

express a neuronal marker (NM) gene, determining expression of the NM gene by mRNA hybridization to a nucleic acid probe, and identifying a test compound for treating neuronal cell death if it decreases expression of the NM gene, classified for example in class 435, subclass 6.

- X. Claims 36 and 38, drawn to a method of identifying candidate drugs for treating neuronal cell death, comprising contacting recombinant host cells transfected with an expression construct which encodes a neuronal marker (NM) gene, determining expression of the NM gene by mRNA hybridization to a nucleic acid probe, and identifying a test compound for treating neuronal cell death if it decreases expression of the NM gene, classified for example in class 435, subclass 6.
- XI. Claims 39 and 40, drawn to a method of identifying candidate drugs for treating neuronal cell death, comprising contacting cells which naturally express a neuronal marker (NM) protein, determining amount of the NM protein in the cells, and identifying a test compound for treating tumors if it decreases the amount of the NM protein in said cells, classified for example in class 435, subclass 7.1.
- XII. Claims 39 and 41, drawn to a method of identifying candidate drugs for treating neuronal cell death, comprising contacting recombinant host cells which are transfected with an expression construct which encodes a neuronal marker (NM) protein, determining amount of the NM protein in the cells, and identifying a test compound for treating tumors if it

decreases the amount of the NM protein in said cells, classified for example in class 435, subclass 7.1.

- XIII. Claims 42 and 43, drawn to a method of identifying candidate drugs for treating neuronal cell death, comprising contacting cells which naturally express a neuronal marker (NM) protein, determining activity of the NM protein in the cells, and identifying a test compound for treating tumors if it decreases the activity of the NM protein in said cells, classified for example in class 435, subclass 7.1.
- XIV. Claims 42 and 44, drawn to a method of identifying candidate drugs for treating neuronal cell death, comprising contacting recombinant host cells which are transfected with an expression construct which encodes a neuronal marker (NM) protein, determining activity of the NM protein in the cells, and identifying a test compound for treating tumors if it decreases the activity of the NM protein in said cells, classified for example in class 435, subclass 7.1.
- XV. Claims 45 and 46, drawn to a method to identify candidate drugs for treating neuronal cell death, comprising contacting cells which naturally express a neuronal marker (NM) gene, determining expression of the NM gene by mRNA hybridization to a nucleic acid probe, and identifying a test compound for treating neuronal cell death if it increases expression of the NM gene, classified for example in class 435, subclass 6.

- XVI. Claims 45 and 47, drawn to a method to identify candidate drugs for treating neuronal cell death, comprising contacting recombinant host cells transfected with an expression construct which encodes a neuronal marker (NM), determining expression of the NM gene by mRNA hybridization to a nucleic acid probe, and identifying a test compound for treating neuronal cell death if it increases expression of the NM gene, classified for example in class 435, subclass 6.
- XVII. Claims 48 and 49, drawn to a method to identify candidate drugs for treating neuronal cell death, comprising contacting cells which naturally express a neuronal marker (NM) protein, determining amount of the NM protein in the cells, and identifying a test compound for treating neuronal cell death if it increases the amount of the NM protein in the cell, classified for example in class 435, subclass 7.1.
- XVIII. Claims 48 and 50, drawn to a method to identify candidate drugs for treating neuronal cell death, comprising contacting recombinant host cells transfected with an expression construct which encodes a neuronal marker (NM), determining amount of the NM protein in the cells, and identifying a test compound for treating neuronal cell death if it increases the amount of the NM protein in the cell, classified for example in class 435, subclass 7.1.
- XIX. Claims 51 and 52, drawn to a method to identify candidate drugs for treating neuronal cell death, comprising contacting cells which naturally

express a neuronal marker (NM) protein, determining activity of the NM protein in the cells, and identifying a test compound for treating neuronal cell death if it increases the activity of the NM protein in the cell, classified for example in class 435, subclass 7.1.

- XX. Claims 51 and 53, drawn to a method to identify candidate drugs for treating neuronal cell death, comprising contacting recombinant host cells transfected with an expression construct which encodes a neuronal marker (NM), determining activity of the NM protein in the cells, and identifying a test compound for treating neuronal cell death if it increases the activity of the NM protein in the cell, classified for example in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-XX are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, Inventions I-XX are directed to methods that are distinct from each other in reagents, steps, and outcomes or functions, and are not required one for the other. For example, the methods of Inventions I-III inhibit or prevent neuronal cell death in a patient, whereas the methods of Inventions VI-VII promote neuronal cell death in a patient, which would require search and examination of specific diseases and patient populations, and the

methods of Inventions IV-V and VIII screen for neuronal cell death in a patient, while the methods of Inventions IX-XX screen for candidate drugs for treating neuronal cell death.

In particular, the method of Invention I recites administering an antibody variable region which specifically binds to a neuronal marker (NM) protein whereas the methods of Inventions II and VII recite administering a nucleic acid molecule and the methods of Inventions III and VI recite administering a purified human neuronal marker protein, each of which differs in structural components (i.e. antibodies, nucleic acids, and proteins) and none of which are required or recited by each other.

The method of Inventions IV, V, and VIII each differ in their administration or contacting steps as well as in their assessment steps (i.e. administration to a patient or contacting a body fluid, and use of a specific binding antibody variable region versus a nucleic acid).

The methods of Inventions IX-XX can further be differentiated based on their distinct measured effects as well as the distinct materials used. Inventions IX-XIV recite identifying candidate drugs that decrease neuronal marker expression, protein amount or activity whereas Inventions XV-XX identify compounds that increase neuronal marker expression, protein amount or activity. Further, different materials (groups of neuronal marker proteins which are used in the screening process) are recited for Inventions IX-XIV versus Inventions XV-XX.

Further, Inventions (X, XII, XIV, XVI, XVIII, and XX) recite the use of recombinant host cells transfected with an expression construct encoding a neuronal marker whereas Inventions (IX, XI, XIII, XV, XVII, and XIX) use cells that naturally express such

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markers. And the methods of Inventions (IX-X and XV-XVI) recite identifying candidate drugs based on detecting mRNA hybridization to a nucleic acid probe, whereas the methods of Inventions (XI-XII and XVII-XVIII) recite detecting NM protein amounts and Inventions (XIII-XIV and XIX-XX) recite detecting NM protein activity as a measure of identifying a candidate drug, each of which involves distinct reagents, steps and effects and are not required, one for another.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for any one group is not required for any other group, restriction for examination purposes as indicated is proper.

### ***Election of Species***

This application contains claims directed to the following patentably distinct species of the claimed invention: disease conditions. The following diseases and conditions are patentably distinct both etiologically and functionally and require separate search and consideration of distinct patient populations:

- a. optic nerve degeneration
- b. Alzheimer's disease
- c. diabetic retinopathy
- d. Huntington's disease

- e. spinal cord injury
- f. Parkinson's disease
- g. glaucoma
- h. age-related macular degeneration

Because these species are distinct for the reasons given above and the search required for one disease or condition is not required for any other disease or condition, election of species for examination purposes as indicated is proper.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 10, 11 and 20 are generic.

**If applicant selects Invention I, II, III, or IV, one species from the disease group (a-h) must be chosen to be fully responsive.**

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Claims 1, 10, 11, 11, 20, 29, 30, 32, 34-36, 39, 42, 45, 48, and 51 are generic to a plurality of disclosed patentably distinct species comprising neuronal markers. The neuronal markers are both structurally and functionally distinct, and the search and examination required for one neuronal marker is not required for any other neuronal marker, and would therefore be burdensome. Therefore, regardless of the invention selected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species or a specific disclosed combination of species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).


***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly A. Ballard whose telephone number is 571-272-4479. The examiner can normally be reached on M-F 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kimberly Ballard, PhD  
Art Unit 1649  
October 27, 2005

  
JANET L. ANDRES  
SUPERVISORY PATENT EXAMINER